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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,161	05/11/2001	Steven M. Ruben	PZ003P3	5950

22195 7590 11/20/2003

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EXAMINER	
KAPUST, RACHEL B	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,161	RUBEN ET AL.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- Th MAILING DATE of this communication appears on th cover sh t with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicants' election of Group IV with traverse and SEQ ID NO: 68, filed March 14, 2003 is acknowledged. Regarding the election of species requirement in Paper No. 0603, Applicants' argument that no claim is directed to an antibody that specifically binds a particular epitope is found to be persuasive. Thus, the requirement for an election of species is withdrawn.

Claims 24-98 are pending in this application.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Also, the current status of all nonprovisional parent applications referenced should be included. The specification needs to be amended to account for Applicant No. 09/152,060 having issued as U.S. Patent 6,448,230.

Specification

The use of the trademarks has been noted in this application. The number of trademarks used in the specification is too numerous to list each one individually. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-98 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial utility or a well-established utility. Claims 24-98 are drawn to antibodies against a protein having the amino acid sequence of SEQ ID NO: 68 and fragments thereof, and isolated cells that produce the claimed antibodies. The claimed antibodies are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

No well-established utility exists for newly isolated, complex biological molecules. The specification does not contain any asserted utilities for the claimed antibodies. Applicants teach that the polypeptides, or fragments or variants thereof can be used as an immunogen to produce antibodies thereto (p. 83). Applicants further teach that the antibodies can be polyclonal, monoclonal, multispecific, human, humanized or chimeric antibodies, single chain antibodies, Fab fragments, F(ab') fragments, fragments produced by a Fab expression library, anti-idiotypic (anti-Id) antibodies, and epitope-binding fragments (p. 89). Applicants further go on to teach generic methods for generating antibodies (p. 88-100). However, nowhere in the specification do Applicants assert an actual utility for the claimed antibodies. As disclosed, the antibodies have the same properties as any other generic antibody. The only possible specific utility of the

claimed antibodies is that they are antibodies against the polypeptides disclosed in the specification.

However, the polypeptides of the invention, to which the antibodies bind, are not supported by either a specific and substantial utility or a well-established utility. The polypeptides are selected from the group consisting of polypeptides having the deduced amino acid sequence of SEQ ID NO: 68, portions of SEQ ID NO: 68, polypeptides encoded by the cDNA of ATCC Deposit No. 97922 and proteins comprising a portion of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 97922. The specification teaches the identification of a cDNA containing an open reading frame encoding a polypeptide that has homology with preprotachykinin B (p. 35). The specification also teaches that the protein was found to be expressed abundantly in human placenta tissue and to a lesser extent in soares placenta.

The specification states that the polypeptide of the invention "is thought to be important in the signal transduction and information processing in the nervous system" (p. 35, lines 2-3). In addition, Applicants teach that tachykinins have smooth muscle contraction and vasodilator effects. While the known tachykinins are expressed in either the central nervous system or peripheral neurons, the polypeptide of the current application was isolated from the placenta. By examining the tissue distribution and according to the homology with preprotachykinin B, Applicants suggest that the polypeptide might be useful for the diagnosis and treatment of reproductive and embroyonic disorders, cancer, Alzheimer's disease, and as a tumor marker or immunotherapy target (p. 36, lines 10-17). Applicants have listed a number of possible activities of preprotachykinin B, but Applicants have not asserted a specific and substantial utility for the protein. Further research would be necessary to assign a utility with the proteins of the invention.

The specification has provided no teaching of the specific function of the protein of SEQ ID NO: 68 or the cDNA of ATCC Deposit No. 97922, *e.g.* the ligand or ligands to which it binds. No specific correlation has been described between the expression of the polypeptides disclosed in the application and a specific disease. Although the specification teaches that a polypeptide was expressed from the cDNA open reading frame, the specification does not teach that the expressed protein was functional nor what that function was.

Applicants teach on p. 35 of the application that the protein of the invention "shares sequence homology with reprotachykinin B." However, the polypeptide of the current application is only 65% identical to preprotachykinin B (see attached alignment). More importantly, little is known about the physiological role played by preprotachykinin B and its receptor, NK3R (see Cintado *et al.* (2001), *J. Pharm. Exp. Ther.* 299(3): 934-938). As Applicants state in their application, the polypeptide comprising SEQ ID NO: 68 may be "an interesting gene to characterize" (p. 35, lines 12-13), but it has yet to be characterized. Consequently, the polypeptides lack a "real world" context of use.

Because the polypeptides are not supported by a specific and substantial asserted utility for the reasons set forth, and the only possible specific utility of the claimed antibodies is binding to the aforementioned polypeptides, a person of ordinary skill in the art would not recognize a utility for the claimed invention.

Claims 24-98 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention because it cannot be determined from the specification how the claimed antibodies would be useful without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-98 are drawn to antibodies that "specifically" bind to proteins of the invention. The term "specifically binds" is a relative term which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount of binding would be considered to be "specific." One skilled in the art would not know what the metes and bounds of specific binding are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-98 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically the cDNA of the clone deposited as ATCC Deposit No. 97922 on March 7, 1997. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials. It is noted that Applicants have deposited the biological materials (p. 57 of the specification), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made

herein. If the deposit has *not* been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years of 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

Applicant's attention is directed to MPEP § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however Applicants are cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicants are advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

Lucas *et al.* (1992), *Neuroscience* 51(2): 317-345

Lang *et al.* (1995), *Regulatory Peptides* 57: 183-192

Hillman *et al.*, U.S. Patent Nos. 6,008,194 and 5,985,606

Lazarus *et al.* (1988), *J. Neuroscience Methods* 23: 161-172

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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